3M ESPE
Dental Products

3M Center
St. Paul, MN 55144-1000
651 733 1110

K073395

3ESPE

JAN 17 2008

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company:	3M ESPE Dental Products
Street:	3M Center Bldg 260-2A-17
ZIP-Code, City:	St. Paul, Mn. 55144
Country:	USA
Establishment Registration Number:	2110898
Official Correspondent:	Karen O'Malley Sr. Regulatory Specialist
Phone:	651 736-7326
Fax:	651 737-6049
E-mail:	kdomalley@mmm.com
Date:	November 21, 2007

Name of Device

Proprietary Name:	GILB-2
Classification Name	Dental Cement 21 C.F.R. §872.3275 as a Class II device.
Common Name:	Dental Cement

Predicate Devices

Device	510(k)
Vitrebond Plus	K011200
Fuji VII Capsule (Fuji Triage)	K013198
Embrace Wetbond Clear Sealant	K052281

Description and Technology Equivalence

GILB-2, Glass Ionomer protective coating is classified as Dental Cement (21 C.F.R§872.3275) because it is a device intended to provide protection as a cavity liner/basing material as well as in treatment of exposed root surfaces hypersensitivity. GILB-2 is a site specific protective coating for newly erupted teeth and other tooth surfaces including non-cavitated lesions.

GILB-2 is a two part liquid/paste system. The liquid/paste materials are contained in the Clicker™ Dispensing System manufactured by 3M ESPE. This dispensing system provides simultaneous dispensing of each component for a consistent mix.

The chemical composition is similar to predicate glass ionomer dental cement devices. The data provided in this 510(k) submission shows that the composition is safe based on the biocompatibility assessment conducted based on ISO10993 and ISO 7405.

The performance testing results provided in the submission confirms the performance as substantially equivalent to the predicate devices with common indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2008

Ms. Karen O'Malley
Senior, Regulatory Specialist
3M ESPE Dental Products
3M Center, Building 260-2A-17
St. Paul, Minnesota 55144-1000

Re: K073395
Trade/Device Name: GILB-2, Glass Ionomer Protective Coating
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Codes: LBH, EJK, EBC, and EMA
Dated: November 21, 2007
Received: December 5, 2007

Dear Ms. O'Malley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

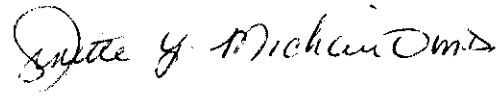
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Print Form

Indications for Use

510(k)Number:K073395

Device Name: GILB-2, Glass Ionomer Protective Coating

Text

Indications For Use:

1. Lining and basing applications under composite, amalgam, ceramic or metal restorations.
2. Treatment of exposed root surface sensitivity
3. Site specific protective coating for newly erupted teeth and other tooth surfaces including non-cavitated lesions

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

K073395